PUMA BIOTECHNOLOGY, INC.
Form 8-K
September 08, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 8, 2017

PUMA BIOTECHNOLOGY, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35703**	**77-0683487**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

10880 Wilshire Boulevard, Suite 2150

Los Angeles, California 90024

(Address of principal executive offices) (Zip Code)

(424) 248-6500

(Registrant s telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On September 8, 2017, Puma Biotechnology, Inc. (the Company) announced positive results from the Phase III clinical trial of the Company s drug neratinib for the extended adjuvant treatment of early stage HER2-positive breast cancer following trastuzumab-based therapy (ExteNET trial). The data was presented at the European Society of Medical Oncology (ESMO) 2017 Congress in Madrid, Spain.

Neratinib was approved by the U.S. Food and Drug Administration (FDA) in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX (neratinib) tablets.

The results showed that the most common adverse reactions (³ 5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.

The ExteNET trial is a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin) in patients with early stage HER2-positive breast cancer. The predefined 5-year invasive disease free survival (iDFS) analysis is a follow-up to the primary 2-year iDFS analysis of the Phase III ExteNet trial.

The ExteNET trial randomized 2,840 patients in 41 countries with early stage HER2-positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomized to receive extended adjuvant treatment with either neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ (DCIS), or death for a period of five years after randomization in the trial.

The patient characteristics in the trial were well balanced between the neratinib and placebo arms of the trial. For the 1,420 patients in the neratinib arm of the trial, 1,085 (76.4%) were node positive while of the 1,420 patients in the placebo arm of the trial, 1,084 (76.3%) were node positive. Additionally, in the neratinib arm of the trial, 816 patients (57.5%) were hormone receptor positive, and in the placebo arm of the trial, 815 patients (57.4%) were hormone receptor positive. The median time from the last trastuzumab dose to entry into the trial was 4.4 months for the neratinib-treated patients and 4.6 months for the placebo-treated patients.

The primary endpoint of the trial was invasive disease free survival (iDFS). The results of the trial demonstrated that after a median follow up of 5.2 years, treatment with neratinib resulted in a 27% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.73, p = 0.008). The 5-year iDFS rate for the neratinib arm was 90.2% and the 5-year iDFS rate for the placebo arm was 87.7%.

The secondary endpoint of the trial was invasive disease free survival including ductal carcinoma in situ (iDFS-DCIS). The results of the trial demonstrated that treatment with neratinib resulted in a 29% reduction of risk of disease recurrence including DCIS or death versus placebo (hazard ratio = 0.71, p = 0.004). The 5-year iDFS-DCIS rate for the neratinib arm was 89.7% and the 5-year iDFS-DCIS rate for the placebo arm was 86.8%.

For the pre-defined subgroup of patients with hormone receptor positive disease, the results of the trial demonstrated that treatment with neratinib resulted in a 40% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.60, p = 0.002). The 5-year iDFS rate for the neratinib arm was 91.2% and the 5-year iDFS rate for the placebo arm was 86.8%. For the pre-defined subgroup of patients with hormone receptor negative disease, the results of the trial demonstrated that treatment with neratinib resulted in a hazard ratio of 0.95 (p = 0.762).

The safety results were unchanged from the primary 2-year iDFS analysis of the study that showed the most frequently observed adverse event for the neratinib-treated patients was diarrhea, with approximately 39.9% of the

neratinib-treated patients experiencing grade 3 or higher diarrhea (1 patient (0.1%) had grade 4 diarrhea). Patients who received neratinib in this trial did not receive any prophylaxis with antidiarrheal agents to prevent the neratinib-related diarrhea. Puma is currently running the ongoing CONTROL trial to investigate the use of loperamide-based prophylaxis to reduce the incidence of grade 3 or higher diarrhea in patients with early stage HER2-positive breast cancer who have completed adjuvant trastuzumab-based treatment. The most recently reported clinical data from CONTROL in June 2017 demonstrated that the use of loperamide-based prophylaxis reduced the rate of grade 3 diarrhea with neratinib, with grade 3 diarrhea rates ranging from 8-31% when loperamide-based prophylaxis was used.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the benefits of NERLYNX and neratinib, the Company s clinical trials and the announcement of data relative to those trials. All forward-looking statements included in this press release involve risks and uncertainties that could cause the Company s actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the fact that the Company has only recently commenced commercialization and shipment of its only FDA approved product; the Company s dependence upon the commercial success of NERLYNX (neratinib); the Company s history of operating losses and its expectation that it will continue to incur losses for the foreseeable future; risks and uncertainties related to the Company s ability to achieve or sustain profitability; the Company s ability to predict its future prospects and forecast its financial performance and growth; failure to obtain sufficient capital to fund the Company s operations; the effectiveness of sales and marketing efforts; the Company s ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates; the challenges associated with conducting and enrolling clinical trials; the risk that the results of clinical trials may not support the Company s drug candidate claims; even if approved, the risk that physicians and patients may not accept or use the Company s products; the Company s reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates; risks pertaining to securities class action, derivative and defamation lawsuits; the Company s dependence on licensed intellectual property; and the other risk factors disclosed in the periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: September 8, 2017

By: /s/ Alan H. Auerbach
Alan H. Auerbach
Chief Executive Officer and President